UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Criminal No. 09-CR-10330-GAO**
	)	
	)	**Violations:**
v.	)	
	)	**18 U.S.C. §2 (aiding and abetting)**
(1) STRYKER BIOTECH, LLC,	)	**18 U.S.C. §371 (conspiracy)**
(2) MARK PHILIP,	)	**18 U.S.C. §1001 (false statements)**
(3) WILLIAM HEPPNER,	)	**18 U.S.C. §1343 (wire fraud)**
(4) DAVID ARD, and	)	**21 U.S.C. §§331(k), 333(a)(2)**
(5) JEFFREY WHITAKER,	)	**and 352 (misbranding)**
	)	
Defendants.	)	

SUPERSEDING INDICTMENT

The Grand Jury charges that:

General Allegations

At all times material to this Superseding Indictment, unless otherwise alleged:

The FDA and FDCA

1. The United States Food and Drug Administration ("FDA") was an agency of the United States government entrusted with responsibility for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans were safe and effective for their intended uses. Pursuant to this statutory mandate, FDA regulated the manufacture, labeling, and shipment in interstate commerce of such devices.

2. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §301-397, the "FDCA"), the term "device" included an "instrument, apparatus, implant, machine

. . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. §321(h).

3. The FDCA required every manufacturer of a new device to obtain "clearance" or "approval" from the FDA prior to marketing and selling its device in interstate commerce.

4. All devices marketed and sold in interstate commerce in the United States fell into one of three regulatory classes under the FDCA. Class III devices were subject to the most stringent regulatory requirements, Class I devices to the least stringent, and Class II devices to requirements that fell in between Class I and Class III. The classification assigned to each device was determined by the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device in its intended use.

5. Devices that were made for commercial distribution after May 28, 1976, when the Medical Device Amendments to the FDCA became effective, were automatically assigned to Class III by operation of law. The FDCA provided four different ways for a manufacturer to obtain approval or clearance to introduce a new device into interstate commerce:

A. Pre-market Approval. Before a company could market a Class III device, that company was required to submit a pre-market approval ("PMA") application to the FDA that provided the FDA with a reasonable assurance that the device was safe and effective when used according to its labeling. 21 U.S.C. §§360e(a)(2) and 360e(d)(2). In order to show safety and

effectiveness, the applicant was required to submit evidence to the FDA, typically in the form of clinical trial results.

B. 510(k) Approval. Alternatively, a company could submit a pre-market notification, commonly referred to as a "510(k)," to the FDA seeking a determination that the device was "substantially equivalent" to a legally marketed Class I or Class II device. 21 U.S.C. §§360c(f) and (i) and 360(k). If the FDA "cleared" the device by determining that the device was substantially equivalent to a device that had demonstrated safety and efficacy, the company could market the device in a manner consistent with the pre-market notification cleared by the FDA. 21 U.S.C. §360c(f)(1).

C. Investigational Device Exemption. This exemption allowed for clinical investigation of devices to determine safety and effectiveness for new uses. 21 U.S.C. §360j(g) and 21 C.F.R. Part 812. Submission, and subsequent approval, of an Investigational Device Exemption ("IDE") permitted a device that would otherwise be required to obtain pre-market approval to be shipped lawfully in interstate commerce for the purpose of conducting clinical investigations.

D. Humanitarian Device Exemption. The fourth option to obtain approval was the submission of an application for a Humanitarian Device Exemption ("HDE"), which was an exemption designed to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of rare diseases or conditions. The HDE application was similar in form and content to a PMA application, but it was exempt from the effectiveness requirements of a PMA. 21 U.S.C. §360j(m). The application, however, was required to contain sufficient information for the FDA to determine that the device did not pose an unreasonable or significant

risk of illness or injury, and that the probable benefit to health outweighed the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant had to demonstrate that no comparable devices were available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. An HDE approval was accompanied by certain additional requirements, among others:

(1) An HDE could only be granted upon a finding by the FDA that the device was designed to treat or diagnose a disease or condition that affected fewer than 4,000 individuals in the United States;

(2) A device approved under an HDE could not be sold for an amount that exceeded the costs of research and development, fabrication, and distribution of the device;

(3) An HDE device could only be used at a medical facility that had established an institutional review board ("IRB") to supervise the clinical testing of devices at the facility; before the use of the device in the facility, the IRB had to approve the use of the device in the treatment of the condition or disease for which the device received the HDE;

(4) When a medical device received an HDE, the holder of the HDE was required to file a periodic report with the FDA that included the number of devices that had been shipped or sold and, if the number shipped or sold exceeded 4,000, to provide an explanation and estimate of the number of devices used per patient, and in turn the number of patients treated. 21 C.F.R.§814.126(b)(1)(iii).

6. Regardless of the type of approval sought from the FDA for a medical device, the manufacturer was required to submit proposed labeling to the FDA for approval. "Labeling"

meant all labels and other written, printed, or graphic matter "(1) upon any article or any of its containers or wrappers or (2) accompanying such article." 21 U.S.C. §321(m). A device manufacturer was not permitted to promote and market a new device until it had an approval not only for the medical device itself, but also for the proposed labeling. The device manufacturer was permitted to promote the device only in accordance with the approved labeling. Uses or methods of use that were not approved by the FDA were "unapproved"or "off-label."

7. Labeling for medical devices was required to contain both (1) adequate directions for use, and (2) adequate warnings, among other warnings, against unsafe methods or application as were necessary for the protection of users. 21 U.S.C. §352(f).

8. A prescription medical device was "adulterated" if it was required to have an FDA approval and did not have the necessary approval.

9. A prescription medical device was "misbranded" if, among other things, its labeling lacked adequate directions for use and it did not qualify for an exemption to this requirement.

10. Introduction or delivery for introduction into interstate commerce of an adulterated or misbranded medical device was prohibited by law. 21 U.S.C. §331(a). When a device was held for sale after shipment in interstate commerce, the law also prohibited the doing of any other act with respect to a medical device that resulted in the device being adulterated or misbranded. 21 U.S.C. §331(k).

The Defendants

11. **STRYKER BIOTECH, LLC** (hereinafter "**STRYKER BIOTECH**") was a limited liability corporation with a principal place of business in Hopkinton, Massachusetts.

STRYKER BIOTECH was a subsidiary of Stryker Corporation, a company whose shares were publicly traded on the New York Stock Exchange.

12. At all relevant times, **STRYKER BIOTECH** was engaged in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) OP-1 Implant, which was an implant to promote growth in certain long bone non-unions; (b) OP-1 Putty, which was a putty to promote bone growth in certain spinal fusions; and (c) Calstrux, which was a bone void filler for surgically created bone defects or bone defects resulting from traumatic injury. **STRYKER BIOTECH** shipped these devices in interstate commerce from its manufacturing facility in New Hampshire to many states, including Massachusetts, California, Florida, Texas, North Carolina, New York, Ohio, Michigan, and others.

13. From approximately April 2004 through approximately February 28, 2008, **MARK PHILIP** ("**PHILIP**") was the President of **STRYKER BIOTECH**.

14. From approximately June 2005 through 2009, **WILLIAM HEPPNER** ("**HEPPNER**") managed the sales force of **STRYKER BIOTECH** under various titles, including National Sales Director. At relevant times, **HEPPNER** was the direct supervisor of **STRYKER BIOTECH's** four Regional Sales Managers, who managed four sales regions: West, Central, Northeast, and Southeast.

15. From approximately June 2005 through 2009, **DAVID ARD** ("**ARD**") was the Regional Manager for the West Region of **STRYKER BIOTECH**.

16. From approximately June 2005 through 2009, **JEFFREY WHITAKER** ("**WHITAKER**") was the Regional Manager for the Southeast Region of **STRYKER BIOTECH**.

The STRYKER BIOTECH Products and FDA Approvals

17. Two of **STRYKER BIOTECH's** products were OP-1 Implant and OP-1 Putty (collectively referred to as "OP-1" or "OP-1 products"). These two devices were part of a class of devices known as bone morphogenic proteins. These proteins had the ability to stimulate, repair, and regenerate bone. OP-1 Implant and OP-1 Putty stimulated natural bone healing by actively recruiting blood supply and stem cells from surrounding tissue and thereby initiating bone formation. OP-1 Implant was designed for use in long bones and was used primarily by trauma surgeons; OP-1 Putty was designed for use in the spine and was used primarily by spine surgeons. The difference between the two devices was that OP-1 Implant was a vial containing a powdery substance that was intended to be used by itself in the long bones, while OP-1 Putty was comprised of a vial OP-1 Implant plus a separate vial of putty additive (230 mg of carboxymethylcellulose), which were intended to be mixed together during surgery to form a putty to place in the spinal gutters during spinal fusion surgery.

18. **STRYKER BIOTECH** initially filed an application for PMA approval of OP-1. With a PMA, **STRYKER BIOTECH** projected a market of hundreds of thousands of patients and hundreds of millions of dollars in potential sales. In response to that application, the FDA notified **STRYKER BIOTECH** that it failed to provide sufficient evidence to support its claims of efficacy, and the PMA application was withdrawn. Failing to obtain the desired PMA approval, **STRYKER BIOTECH** filed an application for an HDE.

19. On October 17, 2001, the FDA granted **STRYKER BIOTECH** an HDE for OP-1 Implant for use as "an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed." A long bone nonunion typically referred to an arm or leg break that did not heal after conventional treatments. "Autograft" referred to bone typically harvested from a patient's hip bone to place and stimulate bone growth in the affected site. Autograft use was unfeasible in certain patients, including elderly patients whose hip and other bones had been weakened from osteoporosis or other conditions. As part of the submission for the HDE, **STRYKER BIOTECH** represented to the FDA that the condition OP-1 Implant was designed to treat affected fewer than 4,000 individuals in the United States. The FDA approved package insert for OP-1 Implant noted "[t]he effectiveness of this device for this use has not been demonstrated."

20. On or about April 7, 2004, the FDA granted **STRYKER BIOTECH** an HDE for OP-1 Putty for use as "an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." "Posterolateral lumbar spinal fusion" referred to a specific type of spinal surgery in which vertebrae in the lumbar (lower back) area of the spine were fused together. "Revision" surgery meant that the patient had already had a surgery that had not succeeded in fusing the vertebrae. Moreover, patients in whom "autologous bone and bone marrow harvest were not feasible or were not expected to promote fusion" were typically those with conditions such as osteoporosis, diabetes, and smokers. As part of the HDE application, **STRYKER BIOTECH** represented to the FDA that OP-1 Putty was designed to treat a condition that affected fewer than 4,000 individuals in the

United States. The FDA approved package insert for OP-1 Putty noted that "the effectiveness of this device for this use has not been demonstrated."

21. Because the OP-1 products were approved under an HDE, no sale of OP-1 could be made to a medical facility until an IRB had considered and approved the use at that facility. Once approved by the IRB, hospitals either purchased one or more of the products outright, or stocked them on a consignment basis. If stocked on a consignment basis, **STRYKER BIOTECH** billed the hospital for OP-1 after receiving a delivered goods receipt that indicated how many units of OP-1 were used in a particular patient during a particular surgery. The hospital paid approximately $5,000 for each unit (or vial) of OP-1 Implant, and $5,250 for each unit of OP-1 Putty (comprised of a vial of OP-1 Implant and a vial of putty additive which represented the additional $250 cost).

22. From in or about 2002 through in or about mid-2004, **STRYKER BIOTECH** received feedback from surgeons that OP-1 handled poorly (like wet sand) and did not provide enough product volume.

23. **STRYKER BIOTECH** then developed another product, Calstrux (originally named "TCP Putty"), a product with a malleable, "silly-putty" type consistency, for, among other reasons, providing surgeons a product that could be mixed with OP-1 as a "carrier" or "extender" to increase the volume and improve the handling qualities of OP-1.

24. Although expecting Calstrux to be mixed with OP-1 as a carrier or extender, **STRYKER BIOTECH** did not seek approval for that use from the FDA. Instead, on or about May 27, 2004, **STRYKER BIOTECH** submitted to the FDA a Section 510(k) pre-market notification of intent to market Calstrux as a bone void filler product. A number of bone void

fillers were then on the market that had been approved for the use of filling voids in bones that resulted from bony defects or injury. No bone void fillers on the market were approved for mixture with bone morphogenic proteins like OP-1.

25. On or about August 26, 2004, the FDA notified **STRYKER BIOTECH** that Calstrux had received a clearance to market the product as "a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous [bony] defects or osseous defects resulting from traumatic injury." Calstrux was not clinically evaluated or cleared for use in combination with other products.

26. **STRYKER BIOTECH** never applied to the FDA for approval of a mixture of OP-1 with Calstrux, nor did the FDA ever approve the mixture.

27. **STRYKER BIOTECH** never performed any clinical trials in humans to determine whether a mixture of OP-1 with Calstrux was safe or effective.

28. **STRYKER BIOTECH** never formulated adequate directions for use for the mixture of OP-1 with Calstrux because the mixture was never approved by the FDA, and accordingly there was no approved labeling for such a mixture.

29. At all times relevant to this Superseding Indictment, **PHILIP, HEPPNER, ARD,** and **WHITAKER** each knew and understood that the FDA had not approved the mixture of OP-1 and Calstrux, that no clinical trial in humans had been conducted to determine whether the mixture of OP-1 and Calstrux was safe or effective, and that no adequate directions for use could be written for the mixture of OP-1 and Calstrux because the mixture was not FDA approved.

Promotion of the Mixture of OP-1 and Calstrux

30. In connection with the company-wide launch of Calstrux in January 2005, **STRYKER BIOTECH** presented Calstrux to the sales force as a "carrier" or "extender" for the OP-1 products, and **PHILIP** noted that the availability of Calstrux should "accelerate" the sales of OP-1.

31. From Calstrux's introduction to the market, **STRYKER BIOTECH** promoted it to surgeons and surgical staff as a product to be used in combination with the OP-1 products, including as a "carrier" or "extender."

32. After launch, the vast majority of all Calstrux sales by **STRYKER BIOTECH** were for mixing with one of the OP-1 products.

33. **PHILIP, HEPPNER, ARD,** and **WHITAKER** promoted and caused to be promoted to surgeons and surgical staff "recipes" or mixing instructions on how to combine Calstrux and OP-1. **STRYKER BIOTECH** employees advised surgeons and/or surgical staff to use various recipes for preparing the mixture of Calstrux and OP-1. Some recommended forming the combination into "cigars," some into "tootsie rolls," some into "logs," some into "bricks," and some into "vienna sausages." The recipes also varied in terms of amount of liquid, type of liquid (blood versus saline), and ratio of Calstrux to OP-1. As one **STRYKER BIOTECH** sales representative wrote to senior management: "Like any product if we have 30+ people doing something different with regards to mixing, dosing etc. we are going to see different results." None of these recipes was ever submitted to the FDA for approval, nor had any been clinically tested in humans to determine whether the mixture was safe and effective for the intended population.

34. Beginning no later than mid-2005, **STRYKER BIOTECH** began to receive reports of adverse events arising from a combination of OP-1 and Calstrux. The events included inflammation, drainage and impaired wound healing. Some patients who experienced these adverse events had to be operated on again, and during some of these subsequent operations, surgeons observed that the OP-1/Calstrux mixture had migrated from the surgical site and looked like "oatmeal," "grits," or "white sesame seeds." In some instances, patients suffered from unwanted bone growth in areas to which the combination of OP-1 and Calstrux had migrated. In some instances, this unwanted bone growth had to be removed surgically.

35. Despite the adverse events associated with the mixture of OP-1 and Calstrux, at the National Sales Meeting in January 2006, **STRYKER BIOTECH** presented a slide to the sales force that described Calstrux as the "perfect carrier for OP-1."

36. In early 2006, **STRYKER BIOTECH** asked a spinal surgeon to prepare an analysis of patients at his hospital who had been treated with a mixture of OP-1 and Calstrux. This analysis, which was communicated to **STRYKER BIOTECH** and **PHILIP** in or about February 2006, demonstrated that patients who received the mixture had an adverse event rate higher than the norm. Later that year, the surgeon further informed **PHILIP** that the mixture was not effective.

37. On or about February 15, 2006, a senior manager at **STRYKER BIOTECH** sent a memorandum about the mixture of OP-1 and Calstrux to other senior managers at **STRYKER BIOTECH,** including **PHILIP**, recounting concerns, including, among others: (a) the adverse events from mixing OP-1 and Calstrux; (b) that a "variety of different 'recipes' are used" by different surgeons; and (c) that Calstrux was being improperly promoted as the "preferred

carrier" for OP-1 by the sales force. This senior manager further made a series of recommendations, including among others: (a) "[c]ease recommending, suggesting and preparing for use Calstrux and OP-1 Implant as noted above. . .", and (b) distribute a "dear doctor" letter advising surgeons about the adverse experiences associated with the mixture of OP-1 and Calstrux.

38. After learning about the recommendation to send a "dear doctor" letter to physicians and IRBs about the adverse experiences associated with the mixture of OP-1 and Calstrux, **HEPPNER, WHITAKER**, and others in sales management argued against that disclosure in part because disclosure would: (a) harm sales of OP-1; (b) anger surgeons who had been misled because "many surgeons are just handed the product prior to implantation and think its all OP-1"; and (c) cause IRBs, whose mission was to protect patients, to cease all OP-1 usage at medical facilities at which they had previously approved the use of OP-1.

39. On or about February 28, 2006, **PHILIP** informed **HEPPNER** by e-mail that no "dear doctor" letter would be sent to IRBs, which **HEPPNER** forwarded by e-mail to **ARD** and **WHITAKER**, among others, noting "[W]e dodged a bullet on this one . . . ."

40. On or about March 1, 2006, a Vice-President of **STRYKER BIOTECH** provided training to the sales force and sales management, including **HEPPNER, ARD** and **WHITAKER**, in which he explained in a powerpoint presentation that the promotion of a mixture of OP-1 and Calstrux could expose the company and individual employees to criminal prosecution, and warned:

"Consequences of 'off-label' promotion

* Company
  - Product recall
  - FDA shut down
  - Criminal misbranding prosecution
  - Enormous criminal fines and civil penalties
* Individual
  - Serious offence [sic], illegal
  - Criminal prosecution and probable fines"

41. On or about March 3, 2006, **PHILIP** informed **HEPPNER** and others at **STRYKER BIOTECH** that no "dear doctor" letter would be sent to surgeons advising them about adverse experiences with the mixture of OP-1 and Calstrux, which news **PHILIP** the next day told a Vice-President of **STRYKER BIOTECH** by e-mail was "positive information" that should be used to ask the sales force to hit their quarterly sales quotas, and which **HEPPNER** told **ARD, WHITAKER**, and others by e-mail makes "this a fantastic day!!!"

42. In or about June 2006, **STRYKER BIOTECH** received a request from the FDA for additional information about adverse events referenced in an annual report for OP-1 Putty; in response to that request, **STRYKER BIOTECH** provided further detail about the adverse events involving the mixture of Calstrux and OP-1, but at no time did **STRYKER BIOTECH** inform the FDA that **STRYKER BIOTECH** had promoted and continued to promote the mixture of Calstrux with OP-1 off-label to surgeons.

43. To respond to the FDA's concern about the adverse events, in or about August 2006, **STRYKER BIOTECH** issued a safety alert regarding Calstrux, in which it noted that a new precaution had been added to the Calstrux FDA-approved labeling which included, among other things, that "Calstrux should not be used in combination with other products."

Accordingly, as of August 2006, the promotion of Calstrux and OP-1 was not only off-label for both OP-1 and Calstrux, but also contrary to the label for Calstrux.

44. Despite knowing that the off-label promotion of the mixture of OP-1 and Calstrux was illegal, and contrary to the precaution in the revised Calstrux label, **PHILIP, HEPPNER, ARD,** and **WHITAKER** continued to promote and cause the promotion of the mixture of OP-1 and Calstrux to surgeons and surgical staff until in or about February 2008.

Annual Reports to the FDA

45. **STRYKER BIOTECH** was required to submit annual reports regarding both OP-1 Putty and OP-1 Implant to the FDA and to include in each of those annual reports information on the number of devices that had been shipped or sold and, if the number shipped or sold exceeded 4,000, provide an explanation and estimate of the number of devices used per patient, and in turn number of patients treated.

46. With regard to OP-1 Putty, in the clinical trials submitted by **STRYKER BIOTECH** to the FDA, each revisionary posterolateral spinal fusion surgery involved use of two units of OP-1 Putty per patient, one for each side of the patient's spine. Therefore, the FDA approved label regarding "Preparations for Use" of OP-1 Putty stated "one unit of OP-1 Putty (1 vial OP-1 Implant/1 vial Putty Additive) will be used on each side of the spine."

47. The cost of using two units of OP-1 Putty (in excess of $10,000) was prohibitive for most surgeries, particularly with a competitor's less expensive bone morphogenic protein on the market. Accordingly, two units of OP-1 Putty per patient were rarely used in spinal surgeries. Most sales of OP-1 Putty were of one unit per patient per surgery.

48. In 2005, **STRYKER BIOTECH** prepared various analyses of the average number of OP-1 Putty units used per patient. These analyses concluded that **STRYKER BIOTECH** was not selling an average of two units per patient, but rather approximately 1.3 units of OP-1 Putty per patient.

49. **STRYKER BIOTECH** knew, as early as February 2005, that based on the actual usage of OP-1 Putty, it could only sell approximately 5,200 units of OP-1 Putty per year (4,000 patients x 1.3 units/patient = 5,200 units). **STRYKER BIOTECH** also knew that there were "[s]ignificant risks associated with exceeding patient limit," including potentially losing the HDE for the product.

50. However, in 2006 and 2007, **STRYKER BIOTECH** adopted sales budgets and quotas that called for sales of more than 5,200 units of OP-1 Putty each year, despite knowing, based on its internal data and analyses, that it could only lawfully sell approximately 5,200 units. Selling an additional 1,000 units of OP-1 Putty, by way of example, would generate additional annual revenue to **STRYKER BIOTECH** of approximately $5 million.

51. By letter dated April 30, 2007, **STRYKER BIOTECH** submitted its 2007 Annual Report for Humanitarian Device Exemption #H0200008 for OP-1 Putty. That report falsely stated as follows:

> Since the last reporting period, 6,234 units of OP-1 Putty have been sold to IRB-approved institutions throughout the United States. Since 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period.

52. On or about October 11, 2007, in connection with an FDA inspection at **STRYKER BIOTECH,** a **STRYKER BIOTECH** employee advised **PHILIP** that the

employee had noticed that the actual usage data for OP-1 Putty did not support the assumption of two units of OP-1 Putty usage per patient, and provided **PHILIP** with an analysis he prepared that day that showed that the average usage per patient was approximately 1.3 units of OP-1 Putty per patient.

53. **PHILIP** asked two subordinates to delete a written analysis they presented to him on or about October 11, 2007 that showed the average usage per patient for OP-1 Putty was approximately 1.3 units.

54. On or about February 20, 2008, in advance of a conference call later that day with management of Stryker Corporation, **PHILIP** asked a colleague to say something on the call that was not true, namely that **STRYKER BIOTECH** had no way to track the per patient usage of OP-1 Putty.

COUNT ONE: 18 U.S.C. §371 – CONSPIRACY

55. The allegations contained in Paragraphs 1 through 54 are realleged and incorporated herein by reference.

56. Beginning no later than February 2006, and continuing thereafter until in or about February 2008, in the District of Massachusetts and elsewhere,

(1) **STRYKER BIOTECH, LLC,**
(2) **MARK PHILIP,**
(3) **WILLIAM HEPPNER,**
(4) **DAVID ARD**, and
(5) **JEFFREY WHITAKER,**

knowingly and willfully did combine, conspire, confederate, and agree with each other and others, known and unknown to the grand jury, to defraud the United States, and its agency, the Food and Drug Administration, by impeding, impairing, obstructing, and defeating through craft, trickery, deceit, and dishonest means the lawful function of the FDA to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the United States were safe and effective for their intended uses; and to commit wire fraud in violation of 18 U.S.C. § 1343.

Objective of the Conspiracy

57. The objective of the conspiracy was to evade and frustrate efforts by the FDA to regulate the safety and efficacy of **STRYKER BIOTECH** medical devices, this objective achieved through the deliberate manipulation of physicians into using an unapproved and untested mixture of OP-1 and Calstrux that was associated with serious adverse events. That deliberate manipulation of physicians was accomplished through illegal off-label promotion of each of OP-1 and Calstrux, and through false and misleading statements made to and omission

and concealment of material facts from medical professionals, medical facilities, IRBs, and the FDA. The purpose of the conspiracy was to obtain millions of dollars of additional revenue from sales of **STRYKER BIOTECH's** products, and as a result, to enrich **PHILIP, HEPPNER, ARD**, and **WHITAKER** through additional compensation and bonuses, and for them to demonstrate the success of **STRYKER BIOTECH** to the corporate parent.

Manner and Means of the Conspiracy

58. It was part of the manner and means of the conspiracy and the scheme and artifice to defraud that **STRYKER BIOTECH, PHILIP, HEPPNER, ARD,** and **WHITAKER,** together with other conspirators known and unknown to the grand jury:

a. launched Calstrux as a product to be mixed with OP-1 products as a "carrier" or "extender" despite knowing that **STRYKER BIOTECH** had never sought FDA approval for such use, and that no clinical trials in humans had been conducted to evaluate the safety or efficacy of the mixture;

b. trained the sales force, including representatives of affiliated companies and distributors, at sales meetings and in the field that Calstrux was an "extender" or "carrier" for OP-1, provided them instructions on how to mix the two products, and encouraged them through commissions, bonuses, sales quotas, employee reviews, field training, and feedback to promote the mixture of OP-1 and Calstrux to physicians;

c. trained the sales force, including representatives of affiliated companies and distributors, at sales meetings and in the field that one unit of OP-1 Putty should be used, despite the fact that the FDA-approved label for OP-1 Putty stated that two units were needed,

and that the only clinical testing in humans conducted by **STRYKER BIOTECH** involved the use of two units of OP-1 Putty;

d. provided surgeons and surgical staff various written instructions for mixing OP-1 and Calstrux, and advised surgeons and surgical staff orally how to mix OP-1 and Calstrux, including in the operating room;

e. at various times, fraudulently induced some surgeons and surgical staff to use the mixture of OP-1 and Calstrux, by providing and making, and causing others to provide and make, materially false statements, and to omit and conceal material facts, including, among others, the following:

(1) misrepresenting various aspects of the mixture of OP-1 and Calstrux, including affirmatively stating that the mixture of OP-1 and Calstrux was "OP-1" when presented to the surgeon;

(2) misrepresenting the nature of the approval of OP-1, including by referring to the HDE for OP-1 as a steppingstone to full approval of OP-1, by stating there was no difference between an HDE and a PMA approval in the physician's ability to use the product off-label, and by claiming the FDA had found OP-1 "necessary;"

(3) misrepresenting that Calstrux was a "carrier," "extender," "additive," or other product that was either an adjunct to or part of the OP-1 device;

(4) failing to disclose that the mixture of OP-1 and Calstrux was not simply OP-1, knowing a surgeon so assumed;

(5) failing to disclose that the mixture of OP-1 and Calstrux had never been approved by the FDA;

(6) failing to disclose that the mixture of OP-1 and Calstrux had never been clinically tested in humans;

(7) failing to disclose the adverse events that were associated with the use of the mixture of OP-1 and Calstrux;

(8) failing to disclose that Calstrux was not approved for mixture with any other product; and

(9) failing to disclose that OP-1 Putty was FDA-approved only for the use of two units per patient, not one unit, and that the only clinical testing in humans on OP-1 Putty was conducted with two units.

e. at various times, concealed and caused others to conceal various material facts from IRBs that were responsible for supervising the clinical testing of devices at medical facilities where OP-1 was used, including, among others: that adverse events had been associated with the use of the mixture of OP-1 and Calstrux; that **STRYKER BIOTECH** employees were promoting a mixture of OP-1 and Calstrux off-label to surgeons and surgical staff and were, in some instances, providing homemade recipes to physicians for mixing the OP-1 with Calstrux; and that surgeons were using OP-1 outside the HDE;

f. hired surgeons as consultants both to speak at physician meetings sponsored by **STRYKER BIOTECH** and to make sales calls on other surgeons to promote the mixture of OP-1 and Calstrux;

g. lulled the FDA into believing the growing number of adverse events from the mixture of OP-1 and Calstrux was being addressed by adding to the Calstrux label a precaution not to use Calstrux in combination with other products, while never informing the

FDA, among other material omissions, that **STRYKER BIOTECH** had been promoting and continued to promote the unapproved mixture of OP-1 and Calstrux to surgeons, and that it had misled and continued to mislead some surgeons into believing that the mixture of OP-1 and Calstrux was all OP-1;

h. promoted a mixture of OP-1 and Calstrux to hospitals and medical facilities through discounted pricing proposals for use of Calstrux as an "extender" with OP-1;

i. took steps to conceal the ongoing conspiracy by directing the sales force to return to the hospitals to retrieve the written mixing instructions that had been previously left behind for the use of the surgeons and surgical staff, while not changing the practice of providing the information to physicians;

j. took steps to conceal the ongoing conspiracy by making a false statement to the FDA in the required 2007 Annual Report about the number of units of OP-1 Putty used to treat patients, thereby hiding from the FDA that the 4000 patient cap had been exceeded;

k. took steps to conceal the ongoing conspiracy by seeking to delete internal company analyses of the number of units of OP-1 Putty used to treat patients, and asking another company employee to lie about **STRYKER BIOTECH'S** capacity to determine the number of units used.

Overt Acts

59. In furtherance of the conspiracy and the scheme and artifice to defraud, **STRYKER BIOTECH, PHILIP, HEPPNER, ARD,** and **WHITAKER**, together with other conspirators, known and unknown to the grand jury, in the District of Massachusetts and elsewhere, committed the following overt acts:

a. On or about March 4, 2006, following the decision not to send a "dear doctor" letter to surgeons notifying them about adverse experiences with the mixture of OP-1 and Calstrux, **PHILIP** advised a senior sales executive to "use the positive information on no Calstrux letter" to aid the sales force in achieving their March 2006 sales quotas;

b. In or about May 2006, **STRYKER BIOTECH** hired an outside surgeon/consultant to attend sales calls on physicians with a sales representative and sales manager in the San Francisco area, during which the physican and the sales representative promoted a mixture of OP-1 and Calstrux, and following which calls the outside surgeon/consultant was congratulated by **STRYKER BIOTECH** because sales were made to some surgeons, and others had specifically agreed to use OP-1 and Calstrux;

c. On or about June 28, 2006, **WHITAKER** approved a proposal to a hospital chain in Florida that included lower prices for OP-1 and a "discounted extender (Calstrux) that provides a larger volume to Infuse. . .";

d. On or about October 23, 2006, **ARD** sent a new **STRYKER BIOTECH** sales representative OP-1/Calstrux mixing instructions;

e. On or about January 15, 2007, **PHILIP** sent the sales managers, including **HEPPNER, WHITAKER ,** and **ARD**, the sales quotas ($68.1 million) and the "Promise to Mark [Philip]" sales figures ($82 million) for 2007, which sales quotas which could only be reached through continued sales of a mixture of OP-1 and Calstrux;

f. By letter dated April 30, 2007, **STRYKER BIOTECH** submitted a 2007 Annual Report for Humanitarian Device Exemption #H0200008 for OP-1 Putty, which falsely stated that in the previous year **STRYKER BIOTECH** had sold 6,234 units of OP-1 Putty and

that "[s]ince 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period. . .";

g. In or about October 2007, **STRYKER BIOTECH** organized an "Emerging Leaders Symposium" in Chicago, Illinois, attended by **HEPPNER**, where **STRYKER BIOTECH** chose the speakers, the content of the conference, and the guest list, and at which symposium unapproved uses of OP-1, including techniques for mixing OP-1 and Calstrux were demonstrated to the physician attendees;

h. In or about October 2007, **PHILIP** asked two subordinates to delete an internal company analysis that they had brought to him on or about October 11, 2007 that showed that the average usage per patient for OP-1 Putty was approximately 1.3;

i. On or about February 20, 2008, in anticipation of a conference call with his supervisor and others, **PHILIP** asked a subordinate to lie and state that **STRYKER BIOTECH** had no way to track the per patient usage of OP-1 Putty; and

j. At various times between March 2006 and February 2008, **STRYKER BIOTECH** and its conspirators provided recipes for mixing OP-1 and Calstrux to different health care professionals, and to employees of affiliated companies and distributors for delivery to health care professionals, including among instances, the following:

1. On or about March 27, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. H.

2. On or about October 17, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. P.

3. On or about October 23, 2006, **WHITAKER** provided to a **STRYKER BIOTECH** sales representative a recipe for mixing OP-1 and Calstrux for delivery to Dr. C.

4. On or about December 11, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. D.

5. On or about March 14, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. M.

6. On or about May 4, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. I.

7. On or about June 29, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Hospital P.

8. On or about August 1, 2007, **ARD** provided to a sales representative of an affiliate a recipe for mixing OP-1 and Calstrux for delivery to Dr. R.

All in violation of 18 U.S.C. §371.

COUNTS TWO THROUGH SIX: 18 U.S.C. §1343 – WIRE FRAUD

60. The allegations contained in Paragraphs 1 through 54, 58 and 59 are realleged and incorporated herein as if set forth in full.

The Scheme to Defraud

61. Beginning on a date unknown, but no later than in or about February 2006, and continuing until at least in or about February 2008, in the District of Massachusetts and elsewhere,

(1) **STRYKER BIOTECH, LLC,**
(2) **MARK PHILIP,**
(3) **WILLIAM HEPPNER,**
(4) **DAVID ARD**, and
(5) **JEFFREY WHITAKER**,

defendants herein, devised and intended to devise a scheme and artifice to defraud physicians and hospitals and to obtain money by means of false and fraudulent pretenses, representations, and promises concerning material facts, and by concealing material facts.

The Purpose of the Scheme

62. The purpose of the scheme and artifice to defraud was for **STRYKER BIOTECH** to obtain millions of dollars in sales from OP-1 and Calstrux, and to enrich **PHILIP, HEPPNER, ARD,** and **WHITAKER** through additional compensation from **STRYKER BIOTECH**, all through the deliberate manipulation of health care professionals with false, deceptive, incomplete, and misleading information into using OP-1 in unapproved and untested ways, including in a mixture with Calstrux.

Manner and Means

63. The allegations contained in Paragraph 58 of the Manner and Means section of Count 1 of this Superseding Indictment are re-alleged and incorporated by reference as though fully set forth herein as a description of the scheme and artifice to defraud.

The Wirings

64. On or about the dates listed below, within the District of Massachusetts and elsewhere,

(1) **STRYKER BIOTECH, LLC**,
(2) **MARK PHILIP**,
(3) **WILLIAM HEPPNER**,
(4) **DAVID ARD**, and
(5) **JEFFREY WHITAKER**,

defendants herein, having devised and intended to devise a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises concerning material facts and matters, and by means of concealing material facts and matters, and for the purpose of executing such scheme and artifice and attempting to do so, knowingly transmitted and caused to be transmitted by means of wire communication in interstate commerce writings, signs, signals, pictures, and sounds to recipients, including recipients in at least the states listed below, on or about the dates set forth below, each instance being a separate count of this Superseding Indictment:

Count	Wiring	To	From	Via
2	2/14/06 e-mail from **WHITAKER** to others at **STRYKER BIOTECH** stating, among other things, "many surgeons are just handed the product prior to implantation and think its [sic] all OP-1."	IL, MO and MA	NC	MA
3	2/27/06 e-mail from **HEPPNER** to **PHILIP**, **ARD**, **WHITAKER** and others urging that a letter warning of adverse effects from a mixture of Calstrux and OP-1 not be sent	MA, CA and PA	IL	MA
4	5/1/06 e-mail from **HEPPNER** to members of **STRYKER BIOTECH** sales force who were lagging on Calstrux sales	AZ, NY and OH	IL	MA
5	10/23/06 e-mail from **ARD** to **STRYKER BIOTECH** sales representative enclosing OP-1/Calstrux mixing instructions	MN	CA	MA
6	1/15/07 e-mail from **PHILIP** to **HEPPNER**, **ARD**, **WHITAKER** and others enclosing 2007 sales budgets	NC, CA and IL	MA	MA

All in violation of 18 U.S.C. §§1343 and 2.

COUNTS SEVEN THROUGH TWELVE: **21 U.S.C. §§331(k), 333(a)(2) & 352(f) - Misbranding a Medical Device**

65. The allegations contained in Paragraphs 1 through 54, 58, and 59 are realleged and incorporated herein as if set forth in full.

66. In the District of Massachusetts and elsewhere, the defendant,

(1) **STRYKER BIOTECH, LLC,**

did, while quantities of OP-1 were held for sale after the devices had been shipped in interstate commerce, and with the intent to defraud and mislead, cause written instructions to be provided for administration and use of a mixture of OP-1 and Calstrux, which was not included in the FDA-approved labeling for OP-1, which acts resulted in OP-1 being misbranded, such instructions being provided by the **STRYKER BIOTECH** sales representative to the physician and/or facility, and containing in part the content, on or about the dates set forth below:

Count	Date	Sales Rep	Doctor/ Facility	Recipe to Mix OP-1 and Calstrux
7	3/27/06	HE	Dr. H	Empty contents of Calstrux vial into OP-1 vial. Thoroughly mix two powders DRY. Add 5cc straight saline, mix, knead until all powder is incorporated.
8	10/17/06	SS	Dr. P	Combine Calstrux vial and both OP-1 vials . . . .Pour all three vials into a small bowl about the size of a specimen cup and mix well to distribute the OP-1 . . . . Add saline (without antibiotic solution) to the bowl and mix well . . . stir well and form into a ball of putty with your hands . . . then divide into two equal parts. Form each part into a Vienna sausage.
9	12/11/06	KL	Dr. D	Mix 2.2 cc blood with the OP-1 and 6 cc straight saline with the Calstrux (separately). Then break the Calstrux in 2 and mix one half with the OP-1, thoroughly.

10	3/14/07	DM	Dr. M	Empty both of the OP-1 Putty units (OP-1 and Putty Additive) into a specimen container. Add 2.5 cc of saline (or the patient's blood). Stir. Add the contents of the Bone Void Filler vial into the container. Add an additional 3cc of saline (or the patient's blood) to the specimen container. Mix the contents.
11	5/4/07	PG	Dr. I	Combine the entire OP-1 (BMP) bottle and the Calstrux bottle in a very small plastic or specimen cup. MIX WELL. Add approx. 4-5 cc's of blood or saline and look at mixture . . . . It should look drier versus runny . . . . [D]ivide the ixture in equal halves (or rolls).
12	8/2/07	JD	Hospital E	Dump OP-1 Putty and Calstrux into a mixing bowl. Mix contents dry first and then add 4cc's of saline (antibiotic mixed in is ok) or blood or aspirate. Continue to mix until OP-1 and Calstrux take putty form . . . .Then roll out into a cigar shape.

All in violation of 21 U.S.C. §§331(k), 333(a)(2), and 352(f).

COUNT THIRTEEN: 18 U.S.C. §1001 - FALSE STATEMENT

66. The allegations contained in Paragraphs 1 through 54, 58.j, 58.k, 59.f, 59.h, and 59.i are realleged and incorporated herein as if set forth in full.

67. By letter dated April 30, 2007, **STRYKER BIOTECH** submitted its 2007 Annual Report for Humanitarian Device Exemption #H0200008 for OP-1 Putty. That report stated as follows:

> Since the last reporting period, 6,234 units of OP-1 Putty have been sold to IRB-approved institutions throughout the United States. Since 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period.

68. On or about April 30, 2007, in the District of Massachusetts and elsewhere,

(1) **STRYKER BIOTECH, LLC**,

defendant herein, did knowingly and willfully make a materially false statement and representation in a matter within the jurisdiction of the executive branch of the United States -- to wit, defendant **STRYKER BIOTECH** falsely reported to the FDA in its 2007 Annual Report for OP-1 Putty the number of units used per patient and a knowingly inaccurate estimate of the number of patients treated, namely that because 6,234 units had been sold and that "[s]ince 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period," when in fact **STRYKER BIOTECH, LLC** knew that less than two units were used per patient and that more than 4,000 patients had been treated during that year.

All in violation of 18 U.S.C. §1001(a)(2).

FORFEITURE ALLEGATIONS
(18 U.S.C. §982(a)(7), 18 U.S.C. §981(a)(1)(C), 28 U.S.C. §2461(c), 21 U.S.C. §334)

69. Upon conviction of one or more offenses alleged in Counts 1 and 13 of this Superseding Indictment, the defendants,

(1) **STRYKER BIOTECH, LLC,**
(2) **MARK PHILIP,**
(3) **WILLIAM HEPPNER,**
(4) **DAVID ARD**, and
(5) **JEFFREY WHITAKER**,

jointly and severally as to Count 1, shall forfeit to the United States, pursuant to 18 U.S.C. §982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

70. Upon conviction of one or more offenses alleged in Counts 2 through 6 of this Superseding Indictment, the defendants,

(1) **STRYKER BIOTECH, LLC,**
(2) **MARK PHILIP,**
(3) **WILLIAM HEPPNER,**
(4) **DAVID ARD**, and
(5) **JEFFREY WHITAKER**,

shall forfeit to the United States, pursuant to 18 U.S.C. §981(a)(1)(C) and 28 U.S.C. §2461(c), any property, real or personal, that constitutes, or is derived from, proceeds traceable to the commission of the offenses.

71. Upon conviction of one or more offenses alleged in Counts 7 through 12 of this Superseding Indictment, the defendant,

(1) **STRYKER BIOTECH, LLC,**

shall forfeit to the United States pursuant to 21 U.S.C. §334 and 28 U.S.C. §2461(c) any quantities of OP-1 and Calstrux, which were introduced into interstate commerce in violation of 21 U.S.C. §§331, 333 and/or 352.

72. If any of the property described in paragraphs 69 through 71 hereof as being forfeitable pursuant to 18 U.S.C. §982(a)(7), 18 U.S.C. §981(a)(1)(C), 28 U.S.C. §2461(c), and/or 21 U.S.C. § 334 as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to 28 U.S.C. § 2461(c) and 18 U.S.C. § 982(b)(1), incorporating 21 U.S.C. § 853(p), to seek forfeiture of all other property of the defendants up to the value of the property described in subparagraphs a through e of this paragraph.

All pursuant to 18 U.S.C. § 982; 18 U.S.C. § 981; 28 U.S.C. §2461(c); 21 U.S.C. §334; and Rule 32.2 of the Federal Rules of Criminal Procedure.

A TRUE BILL

FOREPERSON OF THE GRAND JURY

ASSISTANT U.S. ATTORNEY

DISTRICT OF MASSACHUSETTS; October 11, 2011

Returned into the District Court by the Grand Jurors and filed.

DEPUTY CLERK